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REMARKS

In the First Office Action mailed March 9, 2007, claims 1-69 were pending. Claims 32-69 were withdrawn as being directed to a non-elected invention, and claims 1-31 stand rejected. Claims 32-69 have been cancelled in this response without prejudice to pursuit in one or more divisional applications. Claims 1, 27 and 30 have been amended. Reconsideration of the present application as amended and including claims 1-31 is respectfully requested.

Claims 1-16 and 18-31 stand rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 6,193,721 to Michelson. It is well established that "an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co. Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The claims must not be treated as "mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and that give the claims their meaning." Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al., 730 F.2d 1452, 1459, 221 USPQ 481, 486 (Fed. Cir. 1984). As a result, a reference that coincidentally lists features of a claim without describing the claimed arrangement, relationship, and organization of such features cannot anticipate.

Michelson discloses at least three separate instruments discussed hereinbelow: (1) a pilot hole guide 60, (2) a compression post insertion tool 90, and (3) a compression tool 100. Pilot hole guide 60 is used to form a hole in a vertebral body to receive a bone screw 30. Compression post insertion tool 90 is used to drive a compression post 54 into another vertebral body. Compression tool 100 is used to draw both vertebral bodies toward one another to compress a bone graft provided therebetween. Although pilot hole guide 60, compression post insertion tool 90, and compression tool 100 are used during placement of a plate 2, these separate instruments do not operatively engage each other during use.

Pilot hole guide 60 that includes an outer housing 62 with a lower projecting portion 69 that engages a bone screw hole 6 of plate 2. A central shaft 64 extends through housing 62 and includes a leading end 66 with a pointed tip 65 to penetrate a vertebral body. Pointed tip 65 is used to form a pilot hole that receives a bone screw after pilot hole guide 60 is removed from

bone screw hole 6 of plate 2. The lower end of outer housing 62 can also be threaded to engage a threaded bone screw hole in the plate. See col. 23, lines 40-67 and Figures 31-32.

After plate 2 is engaged to the vertebral body with screws 30 through the bone screw holes 30 and into the pilot holes formed with pilot hole guide 60, compression post insertion tool 90 is used to position compression post 54 through a central locking hole 12 in plate 2 and into another vertebral body. Compression post 54 includes a distally located shaft 56 that extends through central locking hole 12, an intermediate collar 58 that contacts plate 2 to function as a depth stop, and a proximal stem that extends from the collar to a proximal head 55. A groove 59 extends around the proximal stem adjacent head 55. Insertion tool 90 includes a tool shaft 92 with a distally open and proximally closed hollow portion 94 that receives the proximal stem of compression post 54.

During operation of compression post insertion tool 90, force is applied to percussion cap 98 to deliver a driving force to compression post 54 and drive distally located shaft 56 into the vertebral body. When necessary, compression post 54 can be removed from the vertebral body using a lower end 96 of compression post insertion tool 90. Lower end 96 of compression tool 90 includes a recess and depression that engages head 55 to remove compression post 54 from the vertebral body. See col. 24, lines 35-53 and Figs. 33-34.

After compression post 54 is driven into the vertebral body, compression post insertion tool 90 is removed so that compression tool 100 can be positioned around compression post 54. Compression tool 100 includes a second compression arm 130 that is positioned around the proximal stem of compression post 54 and a first compression arm 104 that is engaged to the end of plate 2. Compression tool 100 is operable to move arms 104, 130 toward one another to compress the graft between the vertebral body to which plate 2 is secured with bone screws 30 and the other vertebral body to which compression tool is mounted via compression post 54. See col. 24, line 54 to col. 25, line 12. Compression tool 100 is also employed as a plate holder by engaging arms 104, 130 to opposite sides of plate 2 in notches 142. See col. 20, lines 48-53.

The Office Action asserts that pilot hole guide 60 is the auxiliary element, and that compression post 54/insertion tool 90 is the holding element. There is no disclosure in Michelson that compression post 54 and/or insertion tool 90 are engageable to or positionable

through pilot hole guide 60 or that compression post 54 and/or insertion tool 90 includes a proximal portion engaging pilot hole guide 60 that is operable to rotate pilot hole guide 60 relative to the plate with shaft 56 engaged to the vertebra. There also is no disclosure that compression tool 100 is engaged or engageable to pilot hole guide 60 or insertion tool 90.

Amended claim 1 recites "a stabilization device positionable along a spinal column, said stabilization device including at least one auxiliary element mounted thereto, said at least one auxiliary element including a cannulation extending at least partially therethrough; and a holding element including a distal portion and a proximal portion, said distal portion positionable through said cannulation to engage the spinal column to maintain a positioning of said stabilization device along the spinal column and said proximal portion of said holding element engages said auxiliary element wherein said holding element is operable to rotate said auxiliary element relative to said stabilization device with said distal portion of said holding element engaged to the spinal column." Accordingly, Michelson does not anticipate claim 1 and withdrawal of the rejection of claim 1 is respectfully requested.

Claims 2-16 and 18-19 depend directly or indirectly from claim 1 and are allowable at least for the reasons claim 1 is allowable and for other reasons. For example, claim 9 depends from claim 8 and recites "wherein said holding element engages said auxiliary element and is movable to manipulate said auxiliary device to a desired position relative to said stabilization device." There is no disclosure in Michelson that pilot hole guide 60 is engaged by compression post 54 or insertion tool 90. Claim 10 depends from claim 1 and recites "wherein said holding element includes an intermediate portion between said distal and proximal portions, said intermediate portion including a distally oriented engagement surface for engaging said auxiliary element." There is no disclosure in Michelson that "intermediate portions 90/62" include a distally oriented engagement surface for engaging pilot hole guide 60. Claim 11 depends from claim 10 and recites "wherein said proximal portion of said holding element includes a first driving tool engaging portion proximally adjacent said intermediate portion and a second driving tool engaging portion spaced from said first driving tool engaging portion and adjacent a proximal end of said proximal portion." There is no disclosure that "proximal portion 92" of compression post 54/insertion tool 90 includes driving tool engaging portions as recited in claim 11. Claim 16 depends from claim 15 and recites "said cannulation

extends completely through said auxiliary element; and said distal portion of said holding element extends through said auxiliary element and is engageable with said device when said stabilization device is positioned along the spinal column." Claim 15 recites that the device is positionable between vertebrae of the spinal column. There is no disclosure that distal shaft 56 of compression post 54 is engageable to a device between vertebrae. Claim 19 depends from claim 18 and recites "wherein said proximal portion of said holding element includes a first instrument engaging portion adapted to deliver a rotational force from said instrument to said holding element and a second instrument engaging portion to simultaneously axially secure said instrument to said holding element." There is no disclosure that the compression post 54/insertion tool 90 includes instrument engaging portions arranged as recited in claim 19. Accordingly, withdrawal of the rejection of claims 2-16 and 18-19 is respectfully requested.

Claim 20 recites "a stabilization device positionable along a spinal column and including an auxiliary element associated therewith and movable relative thereto, said auxiliary element including a cannulation extending at least partially therethrough; and a holding element including a distal portion positionable in said cannulation of said auxiliary element, a proximal portion extending proximally from said distal portion, and an intermediate portion therebetween, wherein said intermediate portion includes a distally oriented engagement surface adapted to engage said auxiliary element, said holding element movable to position said auxiliary element in a desired position relative to said stabilization device." The Office Action asserts that pilot hole guide 60 is an auxiliary element and that compression post 54/insertion tool 90 are the holding element. As discussed above, there is no disclosure that shaft 56 or any other portion of compression post 54/inertion tool 90 includes a distal portion positionable in any cannulation of pilot hole guide 60. Nor is there any disclosure that compression post 54/insertion tool 90 includes any distally oriented engagement surface that is adapted to engage pilot hole guide 60 or that compression post 54/insertion tool 90 is movable to position pilot hole guide 60 in a desired position relative to bone plate 2. Accordingly, a prima facie case for rejecting claim 20 as anticipated by Michelson has not been established, and withdrawal of this basis of the rejection of claim 20 is respectfully requested.

Claims 21-26 depend from claim 20 and are allowable at least for the reasons claim 20 is allowable and for other reasons. For example, claim 23 recites "wherein said proximal portion of

said holding element includes a first driving tool engaging portion proximally adjacent said intermediate portion and a second driving tool engaging portion spaced from said first driving tool engaging portion and adjacent a proximal end of said proximal portion." Recesses 142 are formed on the arms 104, 130 of the compression tool 100 and are provided to grab the sides of the plate. There is no disclosure that recesses 142 are driving tool engaging portions, or that one of the recesses is adjacent a proximal end of the proximal portion of the holding element and the other is proximal adjacent the intermediate portion of the holding element. Claim 26 recites "wherein said proximal portion of said holding element includes a first instrument engaging portion adapted to deliver a rotational force from an instrument to said holding element and a second instrument engaging portion adapted to axially secure the instrument to said holding element" and is not disclosed as discussed above with respect to claim 19. Accordingly, withdrawal of the rejection of claims 21-26 depending from claim 20 is respectfully requested.

Amended claim 27 recites "a holding element including a distal portion positionable in a cannulation of the stabilization system, a proximal portion extending proximally from said distal portion, and an intermediate portion therebetween, wherein said proximal portion of said holding element includes a first instrument engaging portion adapted to receive a rotational force delivered to said holding element and a second instrument engaging portion spaced from said first instrument engaging portion adapted to receive an axial force delivered to said holding element." Michelson discloses that compression post 54 includes a proximal stem that is received in the closed hollow portion 94 of compression post insertion tool 90, and that the compression post insertion tool 90 is used to drive compression post 54 into the vertebral body. Recess 99 and depression 97 grab head 55 to pull compression post 54 from the vertebral body. There is no disclosure that the stem of compression post 54 includes the first and second instrument engaging portions adapted to deliver rotational and axial forces as recited in claim 27. Furthermore, pilot guide 60 includes shaft 64 that is axially driven into the vertebral body to form a pilot hole by impacting head 68 and that shaft 64 is proximally biased in housing 64 with spring 67. There is no disclosure that shaft 64 includes the first and second instrument engaging portions adapted to receive rotational and axial forces delivered to shaft 64 as recited in claim 27. In addition, compression tool 100 includes arms 104, 130 with notches 142 to grab the sides of the plate. Arms 104, 130 include passages to slide along

the proximal end of compression post 54. However, there is no disclosure of any structure on compression post 54 that engages arms 104, 130 such that compression post 54 could be properly considered to include first and second instrument engaging portions adapted to receive rotational and axial forces as recited in claim 27. Accordingly, withdrawal of this basis of the rejection of claim 27 is respectfully requested.

Claim 28-31 depend from claim 27 and are allowable at least for the reasons claim 27 is allowable and for other reasons. For example, claim 28 recites "wherein said intermediate portion includes a distally oriented engagement surface adapted to engage an auxiliary element of the stabilization system and deliver a manipulation force thereto." There is no disclosure that collar 58 includes a distally oriented engagement surface adapted to engage an auxiliary element of the stabilization device to deliver a manipulation force. Claim 30 recites "wherein said proximal portion includes a shaft and said first instrument engaging portion is positioned adjacent said intermediate portion at a distal end of said shaft and said second instrument engaging portion is positioned adjacent a proximal end of said shaft." The Examiner does not indicate how it is considered that Michelson discloses instrument engaging portions arranged as recited in claim 30. Claim 31 depends from claim 30 and recites "wherein said first instrument engaging portion includes a head shaped to receive a tool thereover and said second instrument engaging portion includes a recess about said shaft." The Examiner does not indicate how it is considered that Michelson discloses a holding element with instrument engaging portions arranged as recited in claim 31. Accordingly, withdrawal of the rejection of claims 28-31 depending from claim 27 is respectfully requested.

Claim 17 stands rejected as being unpatentable under 35 USC §103(a) over Michelson in view of U.S. Patent Application Publication No. 2003/0083749 to Kuslich et al. Claim 17 depends from claim 1 and is allowable at least for the reasons claim 1 is allowable. Accordingly, withdrawal of the rejection of claim 17 is respectfully requested.

The present application including claims 1-31 is in condition for allowance, and a Notice of Allowance is respectfully requested. The Examiner is welcome to contact the undersigned to resolve any outstanding issues with respect to the present application.

Respectfully submitted,

By: Douglas A. Collier

Douglas A. Collier
Reg. No. 43,556
Krieg DeVault LLP
One Indiana Square, Suite 2800
Indianapolis, Indiana 46204-2079
(317) 238-6333 (voice)